

REMARKS

I. INTRODUCTION

Claims 1-5, 7, 8, 10-15 and 17-26 remain pending in the present application. No new matter has been added. In view of the following remarks, it is respectfully submitted that all of the presently pending claims are allowable.

II. THE 35 U.S.C. § 102(e) and 35 U.S.C. § 103(a) REJECTION SHOULD BE WITHDRAWN

Claims 1-5, 7, 8, 10, 12-15 and 17-26 stand rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent Publication No. 2003/0097167 to Friedman ("Friedman") or, in the alternative, under 35 U.S.C. 103(a) as obvious over Friedman in view of U.S. Patent No. 7,008,419 to Shaddock ("Shaddock"), or in view of U.S. Patent No. 6,855,116 to Atlee III ("Atlee"), or in view of U.S. Patent No. 6,266,549 to Melnikoff et al. ("Melnikoff") or in view of U.S. 7,212,867 to Van Venrooij et al. ("Van Venrooij"). 9/25/07 Office Action, pp. 2-3.

Claim 1 recites a medical apparatus comprising "a flexible probe for accessing a patient's esophagus via the mouth, the probe, when in an operative position, extending from a proximal end which remains outside the patient to a distal end within the esophagus" in combination with "an echocardiography transducer coupled to the distal end of the probe so that, when the probe is in the operative position, the echocardiography transducer is at a predetermined location within the esophagus relative to the heart to perform a transesophageal echocardiography procedure" and "a flexible sheath sized to be received one of permanently and removably over the probe, *the sheath including a non-annular electrode so that the electrode, when in an operative position, contacts the esophagus to deliver a cardioversion current to the heart.*"

In contrast, Friedman discloses an esophageal probe with annular electrode rings that are clamped over a silicone sheet assembly wrapped around a distal end of the probe. Friedman

describes the distal portion 14 of an elongated flexible member 10 as being wrapped with a silicone sheet subassembly 30 that contains electrical contacts 25 and conductors 24 to each contact 25. *Friedman*, p. 3, ¶ [0031]. Clamped over the silicone sheet subassembly 30 are electrode rings 26, which *Friedman* describes as “annular.” *Id.* at ¶ [0031] and [0032]. Specifically, *Friedman* teaches that the “[a]nnular rings are circumferentially disposed about the distal portion 14.” *Id.* at ¶ [0031]. The non-annular electrode disclosed in claim 1, on the other hand, has a length extending a short distance along the length of the probe, as is shown, for example, in the embodiment of Fig. 3b.

The Examiner points to Fig. 5 to contend that the electrode assembly of *Friedman* is C-shaped and non-annular. 9/25/07 *Office Action*, p. 3. However, it is respectfully submitted that the term “annular” will be interpreted by those of skill in the art to refer to any substantially ring-like structure that extends nearly entirely around a circumference, even if it is not a completely closed ring. The dimensions of the electrode ring 26 in Fig. 5 shows an inner radius of 266, an outer radius of 306 and an opening of just 094. Such dimensions would indicate that the opening is quite minimal and that the opening appears larger in the drawing than it actually is. Although the electrode ring 26 does not form a full 360 degree construction, it is respectfully submitted that the small opening of the electrode ring renders it substantially ring-like, as evidenced by *Friedman*’s use of the term annular, and would be considered annular by those of skill in the art.

The Examiner also contends that the electrical contacts 25 of *Friedman* are capable of functioning as an electrode and are non-annular. 9/25/07 *Office Action*, p. 3. Although the electrical contacts 25 may be formed in the sheet assembly 30, it is respectfully submitted that nowhere in the specification of *Friedman* are the electrical contacts 25 described as electrodes or as being used as electrodes. They are used merely as contact points for the electrode rings 26. *Friedman* at ¶ [0033].

Thus, it is respectfully submitted that *Friedman* does not teach or suggest a “*sheath including a non-annular electrode*,” as recited in claim 1. Therefore, it is respectfully submitted

that claim 1 is not anticipated by Friedman and the § 102(e) rejection of this claim should be withdrawn. Because claims 2-5, 7, 8, 10, 12-13 and 24-26 depend from and, therefore, include all of the limitations of claim 1, it is respectfully submitted that these claims are also allowable.

In the alternative, the Examiner asserts that it would have been obvious to combine the device of Friedman with a non-annular electrode. *9/25/07 Office Action*, pp. 3-5. The Examiner specifically cites Shaddock, Atlee, Melnikoff and Venrooij to show non-annular electrodes with which the device of Friedman may be combined. *Id.* However, it is respectfully submitted that because Friedman specifically teaches an annular ring, it would not have been obvious to one of ordinary skill in the art to combine the probe of Friedman with a non-annular electrode. The non-annular electrode with limited surface areas as recited in claim 1 has the advantage of being positioned in specific areas of the esophagus and thus can apply energy to only a selected area of the heart. There is no suggestion in Friedman that such an arrangement or result is desirable. Indeed, Friedman teaches the use of a large surface area electrode for cardioversion using a transesophageal probe. *Friedman*, p. 8, ¶ [0076]. As shown in Fig. 4, the apparatus of Friedman is capable of recording/pacing and shocking, which would necessitate the use of a large surface area electrode. As annular electrodes provide the greatest surface area, there is no teaching, suggestion or motivation to modify Friedman with a non-annular electrode, which has a smaller surface area. Thus, it would not have been obvious to one of ordinary skill in the art to modify Friedman's apparatus with a non-annular electrode.

It is respectfully submitted that even if, however, the device of Friedman could be modified, Shaddock, Atlee, Melnikoff and Venrooij do not cure the deficiency of Friedman.

Shaddock discloses a treatment device 5 for thermally mediated alteration of the cellular/extracellular architecture of a lower esophageal sphincter. *Shaddock*, col. 7, ll. 37-41. The device 5 comprises an extension member 10 with a proximal end 11 and a working end 15, which includes at least one electrode. *Id.* at col. 7, ll. 41-43 and col. 8, ll. 5-8. The electrodes disclosed in Shaddock, however, are used to treat walls of the lower esophageal sphincter by

inducing an injury-healing response, while the electrodes of Friedman are used to provide pacing and cardioversion therapy. Cardioversion therapy requires the electrode to send electrical signals through the wall of the esophagus, while treatment of the lower esophageal sphincter limits the electrode therapy to the lumen of the esophagus. These are two drastically different procedures. Thus, the electrode of Shadduck would not be appropriate for the device of Friedman, as it would not be able to send electrical signals through the wall of the esophagus. Thus, it is respectfully submitted that Friedman and Shadduck, either alone or in combination, do not show or suggest a *"the sheath including a non-annular electrode so that the electrode, when in an operative position, contacts the esophagus to deliver a cardioversion current to the heart,"* as recited in claim 1.

Atlee discloses a carrier member 88 that has a pair of ring-type electrodes 90 engaged with the outer wall of carrier member 88. *Atlee*, col. 8, ll. 9-12. As evidenced by Atlee's use of the term "ring-type electrodes," it is respectfully submitted that the opening in the ring 90 is very small and that the electrode is substantially ring-like and thus annular. This is further evidenced by the description of carrier member 22, which is generally similar in construction with carrier member 88, which states that a user should spread wings 42,44 of the carrier 22 apart such that an opening of space between ends 36, 38 becomes large enough to receive a stethoscope 20. *Id.* at col. 6, ll. 33-38 and col. 8, ll. 8-9. Fig. 10 shows that electrode 90 engages almost the entire circumference of carrier 88. Therefore, it is respectfully submitted that the opening in ring-type electrode 90 is very small and would be considered by those of ordinary skill in the art to be annular. Accordingly, it is respectfully submitted that Atlee does not teach or suggest a *"sheath including a non-annular electrode so that the electrode, when in an operative position, contacts the esophagus to deliver a cardioversion current to the heart,"* as recited in claim 1 and thus does not cure the deficiency of Friedman.

Melnikoff discloses an electrode 17 comprising an electrode dome 50 arranged on a unitary base 52, which further comprises an annular ring having an aperture 54 passing therein. *Melnikoff*, col. 6, ll. 11-17. The electrode dome 50 is integrally formed with the ring 52. *Id.* at

col. 6, ll. 16-21. Melnikoff teaches that both the electrode domes 50 and annular base 52 are comprised of a homogeneous metal that prevents the electrode dome 50 and base 52 from developing different polarities. *Id.* at col. 6, ll. 26-29. Thus, it is respectfully submitted that the annular base 52 and the electrode dome 50 together function as an electrode 17 and that the electrode assembly 50, 52 essentially forms an annular electrode. Therefore, it is respectfully submitted that Melnikoff does not teach or suggest a “*sheath including a non-annular electrode so that the electrode, when in an operative position, contacts the esophagus to deliver a cardioversion current to the heart,*” as recited in claim 1. Accordingly, it is respectfully submitted that Melnikoff does not cure the deficiency of Friedman.

Van Venrooij discloses a directional brain stimulation lead assembly for implantation in the brain. It is respectfully submitted that it would not have been obvious to one of ordinary skill in the art to modify the device of Friedman, an esophageal probe, with the electrodes of Van Venrooij since they serve drastically different purposes. Moreover, the lead assembly of Van Venrooij provides a windowed insulating member 10 that has a substantially tubular body 12 with a window 16 such that when the insulating member 10 is placed over a lead body 20, portions of electrodes 24 are exposed. *Van Venrooij*, col. 6, ll. 34-40. The Examiner specifically points to Figs. 3, 4, 6 and 18 to show non-annular electrodes. *9/25/07 Office Action*, p. 4. However, it is respectfully submitted that the electrodes 24 shown in these figures extend 360 degrees about the lead body. *Van Venrooij* at col. 6, ll. 1-5. The electrodes only appear to be non-annular because of the cut-out windows 16. As noted by the Examiner, Van Venrooij indicates that C-shaped ring electrodes may be used instead, but it is respectfully submitted that Van Venrooij specifically teaches that these electrodes should be embedded into the lead body. *Id.* at col. 15, ll. 38-41. Thus, it is respectfully submitted that even if the C-shaped electrodes taught by Venrooij were combined with Friedman, the C-shaped electrodes could not possibly be crimped over the sheet subassembly described by Friedman. Accordingly, neither Friedman nor Venrooij, either alone or in combination, show or suggest a “*sheath including a non-annular electrode so that the electrode, when in an operative position, contacts the esophagus to deliver a cardioversion current to the heart,*” as recited in claim 1.

Furthermore, it is respectfully submitted that it would not have been obvious to one of ordinary skill in the art to use the electrical contacts 25 of Friedman as electrodes since Friedman specifically teaches that the electrode rings 26 should be crimped over the distal portion 14 to correspond with the electrical contacts 25. *Friedman* at ¶ [0033]. They are used merely as contact points for the electrodes. *Id.* Thus, there is absolutely no teaching, suggestion or motivation to use the electrical contacts 25 as electrodes.

Therefore, it is respectfully submitted that claim 1 is not rendered obvious by Friedman alone or by Friedman in view of Shadduck, Atlee, Melnikoff or Venrooij and that the § 103(a) rejection of this claim should be withdrawn. Because claims 2-5, 7, 8, 10, 12-13 and 24-26 depend from and, therefore, include all of the limitations of claim 1, it is respectfully submitted that these claims are also allowable.

Similarly, claim 14 recites a cardioversion mechanism comprising “a flexible sheath sized to be received one of permanently and removably over a transesophageal echocardiography probe, *the flexible sheath including a non-annular electrode assembly*, wherein, when the sheath is received by the echocardiography probe, electrodes of the electrode assembly are located at a predetermined location with respect to the echocardiography probe, *the electrode assembly being coupled to a power source for supplying a cardioversion current to a heart by contacting tissue located adjacent thereto when the echocardiography probe is in an operative position within an esophagus of a patient.*”

For the same reason as discussed above in regard to claim 1, it is respectfully submitted that claim 14 is neither anticipated by Friedman nor rendered obvious by Friedman in view of Shadduck, Atlee, Melnikoff or Venrooij and that the rejections to this claim should be withdrawn. Because claims 15 and 17-19 depend from and, therefore, include the limitations of claim 14, it is respectfully submitted that these claims are also allowable.

Claim 20 recites a method comprising a “inserting into the patient’s esophagus a device

comprising a flexible probe having an echocardiography transducer coupled to a distal end thereof and a flexible sheath sized to be received one of permanently and removably over the probe, *the sheath including at least one non-annular cardioversion electrode*” in combination with “performing an echocardiography to analyze a condition of the heart” and “applying electric current to the at least one electrode to supply a cardioversion current to the heart by contacting the electrode to the esophagus when the echocardiography does not contraindicate cardioversion. sheath including at least one non-annular cardioversion electrode.”

As discussed above in regard to claims 1 and claim 14, it is respectfully submitted that claim 20 is neither anticipated by Friedman nor rendered obvious by Friedman in view of Shaddock, Atlee, Melnikoff or Venrooij and that the rejections to this claim should be withdrawn. Because claims 21-23 depend from and, therefore, include the limitations of claim 20, it is respectfully submitted that these claims are also allowable.

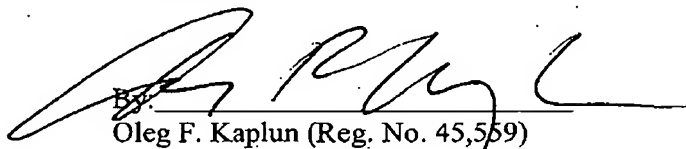
Claim 11 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Friedman or, in the alternative, as unpatentable over Friedman in view of Shaddock. 9/25/07 Office Action, p. 7. As discussed above, Friedman does not disclose or suggest “a sheath including a non-annular electrode,” as recited in claim 1, from which claim 11 depends. Accordingly, it is respectfully submitted that claim 11 is allowable as being dependent on an allowable base claim and that the Examiner should withdraw the 35 U.S.C. § 103(a) rejection of claim 11.

CONCLUSION

In light of the foregoing, Applicant respectfully submits that all of the presently pending claims are in condition for allowance. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

Dated: December 21, 2007


By: _____
Oleg F. Kaplun (Reg. No. 45,559)

Fay Kaplun & Marcin, LLP
150 Broadway, Suite 702
New York, New York 10038
Tel: (212) 212-619-6000
Fax: (212) 619-0276